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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,708	06/16/2006	Stefan Bracht	RO4101US	5800

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

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05/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,708	BRACHT, STEFAN	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *5-8,11 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 9, 10, 12-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/17/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's election filed 03/15/2010; and IDS filed 10/17/2005.

Claims 1-15 are pending.

Response to Election/Restrictions

1. Applicant's election with traverse of invention of group I and species (a), claims 1-4, 9, 10, 12-14, in the reply filed on 03/15/2010 is acknowledged. The traversal is on the ground(s) that the present claims meet the requirements of PCT Rule 13.2 according to which the requirement of unity of invention is met when there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features. Independent method claim 11 references claim 1, thus involving the same technical features as claim 1.

This is not found persuasive because the process of group II requires more than one system that are different in terms of concentration of dyes and/or pigments, and are different in terms of type of the dyes and/or pigments, which are not required by invention of group I. Further, the process of group II does not require active ingredient that is colorless in initial state and discolors during storage or application period, which is required by group I. The process of group II does not produce transparent or

translucent patch as required by the patch of group I. The process of group II does not require any of the specifics as claimed by claims 2-10, 12 -14 of group I. Therefore the process claims do not provide all the criteria of the claimed product and the process claims do not commensurate in scope with the product claims. Further, coating of lacquer containing dye is distinguished from materials that reflect light hat may be aluminum layer.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 5-8, 11, and 15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 03/15/2010.

Claims 1-4, 9, 10, 12-14 are included in the prosecution.

Specification

3. The use of the trademark “Naturell BB PIV” and “Naturell pulver”, “Durotak 2052”, “Scotchpak 1006” has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Information Disclosure Statement

4. The information disclosure statement filed 10/17/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. However, the references have been considered and are listed on the attached PTO-892 in order to have the references printed on any patent resulting from this application.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-4, 9, 10, 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recites “dyes and pigments” and the specification gives no guidance to one of ordinary skill in the art regarding any dyes and pigments except for two art-unknown trademark/name “Naturell BB PIV” and “Naturell pulver”. Applicant is required to provide description for the unknown trademarks. The specification does not describe dyes and pigments suitable

to practice the present invention. Claiming dyes and pigments without partial or complete description of any dyes or pigments does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter specially the claims recite "transparent or translucent" patch. How the transparent or translucent patch contain dyes or pigments? Therefore, the claims limitations are not correlated in order to meet the written description requirement. One of ordinary skill in the art could not recognize or understand the dyes and pigments suitable to practice the present invention from their mere recitation. Claims employing limitation at the point of novelty, such as applicant's, neither provide those elements required to practice the inventions, nor "inform the public" during the life of the patent of the limits of the monopoly asserted. The terms "dyes and pigments" could encompass myriad of compounds and materials, known and unknown, and applicant terms represents only an invitation to experiment regarding possible dyes and pigments.

To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. *Vas-Cath Inc. v Mahurkar*, 19 USPQ 2d 1111. The invention is, for purpose of the "written description" inquiry, what ever is now claimed (see page 1117). The specification does not clearly allow person of ordinary skill in the art to recognize that [he or she] invented what is claimed (see *Vas-Cath* at page 116). One cannot describe what one has not conceived. See *Fiddes v Baird*, 30 USPQ2d 1481, 1483.

Regarding the requirement for adequate written description of chemical entities, Applicants' attention is directed to MPEP § 2163. In particular, *Regents of the University of California v. Eli Lilly & Co.,* 119 F. 3d 1559, 1568 (Fed. Cir. 1997), cert denied, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish list or plan for obtaining the claimed chemical invention." *Eli Lilly*, 119 F. 3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the U.S.C. 112.1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including inter alia, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem Inc. v. Gen-Probe Inc.*, 296 F. 3d 316, 1324-25 (Fed. Cir. 2002) (quoting Guidelines, 66 Fed. Reg. At 1106 (emphasis added)). Moreover, although *Eli Lilly and Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.,* 249 Supp. 2d 216,225 (W.D.N.Y. 2003).

7. Claims 1-4, 9, 10, 12-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nicotine as pharmaceutically active substance provided transdermal patch comprising Durotak 2052 polymer matrix and

PET film having 15 μm thickness in order to provide transparent or translucent patch as disclosed by the current example, does not reasonably provide enablement for all or any other pharmaceutically active substance, polymer matrix or backing materials of any other thickness. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention: The invention provides a medical active substance patch comprising a matrix of monolayer or multilayer configuration and a backing layer connected with said matrix, wherein at least one layer of the matrix contains an active substance, and wherein at least one layer of the matrix contains at least one coloured ingredient which is coloured, or which is colourless in an initial state and which has a tendency to discolour or which discolour(s) during storage or during the application period; said active substance patch being is transparent or translucent; said

active substance patch comprises at least one substance selected from the group consisting of dyes and pigments in at least one of said layers; in the state of having been applied to a first person's skin said patch, at a place of the skin covered with the patch, has a lightness colour value L1 which is not less than 50% and not more than 200% of a lightness colour value L2, with L2 being the lightness value of the region of the skin of the same person which surrounds the applied patch, and that the same applies in respect of the skin of a second or any other person, provided that L2 is in the range from 5° to 100°.

(2) The state of the prior art: The art recognized transparent nicotine patch that does not contain pigments, see US 7,622,136 for Gale, and also recognized transparent patch containing UV absorber, see DE 10053375 for Degen. The art however does not recognize transparent patch containing dyes or pigments.

(3) The relative skill of those in the art: The relative skill of those in the transdermal art is high.

(4) The predictability or unpredictability of the art: The unpredictability of the art regarding transparent patches comprising dyes and pigments in their matrix and backing layer and contains any drugs and pharmaceutical agents, any matrix polymer and any backing materials is very high.

(5) The breadth of the claims: The claims are broad. The claims encompass all drugs and pharmaceutical agents, known and unknown, all polymers and backing materials containing any known or unknown dyes and pigments delivered in the claimed transdermal device in all the possible combinations, yet provide transparent patch.

(6) The amount of direction or guidance presented: The specification and the sole example disclose nicotine only as pharmaceutical agent, Durotak 2052 as polymer matrix and PET of specific thickness as backing material to provide transparent or translucent patch when combined with pigment. The specification does not disclose any other pharmaceutical agents that are colorless in initial stage and have tendency to change color during storage and use, any other matrix material and backing materials other than listed above that can be combined with the disclosed unknown pigments or dyes and provide transparent patch having the claimed lightness color values. The specification has failed to provide guidance regarding any other drug or pharmaceutical agent, any polymer matrix combined with pigment or dye and any backing containing dye or pigment, yet the patch is transparent or translucent and having the claimed lightness color values. It is not obvious from the disclosure of nicotine in Durotak 2052 matrix and PET backing of 15 μm thickness if all other drugs and pharmaceuticals, polymers or backing materials will work with any dye or pigment to provide transparent patch. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the diets fall within the scope of the claims will possess the alleged activity. See *In re Riat et al*. (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al*. (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

(7) The presence or absence of working examples: As stated above, the specification discloses only nicotine in Durotak 2052 matrix and PET backing of 15 μm thickness wherein the matrix and backing containing pigments. Therefore, the specification does not enable all drugs and pharmaceutical agents, all polymers or all

backing materials, all dyes or pigment to provide transparent transdermal patch. Pharmaceutical agents and polymers vastly vary in their properties and reactivity with all dyes and pigments that encompassed by the claims.

(8) The quantity of experimentation necessary: Since the effect of all dyes and pigments on all drugs and pharmaceuticals, polymers and backing materials encompassed by the claims in all possible combinations can not be predicted, but must be determined from the case to case by experimental study on what drug or polymers, or backing materials can be combined with what dye or pigment, and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue experimentation to determine the transdermal patch as instantly claimed.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-4, 9, 10, 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are confusing because while the claims recite transparent or translucent patch, the claims also recite inclusion of dyes and pigments in all the layers of the patch. How the patch containing dyes and pigments will be transparent?

Regarding the lightness color value and their measurement, it is not clear to the examiner regarding what degree used to measure 5^{o} to 100^{o}. Where values can vary depending on the basis for their determination, the claimed subject matter may be

indefinite. *See Honeywell Intl. v. Intl. Trade Commn.*, 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that, where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the value is indefinite when the claim fails to concurrently recite the method of measurement used to obtain it). Accordingly, the values recited by instant claims are incomplete insofar as they do not specify the frame of reference used to measure them.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-4, 9, 10, 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Degen (DE 10053375, translation currently provided) as evident by the provided articles: “4-aminobenzoic acid”, encyclopedia, “CINNAMIC ACID”, product identification, “Benzophenone”, IngredientsFeedbackScience, and “Lacquer definition”, Your Dictionary.

Degen discloses transparent transdermal therapeutic system (TTS) contain photosensitive active ingredient. The TTS comprises colorless active ingredients contained polymer matrix and has a backing layer. The matrix and the backing comprise UV absorbent that does not have pharmacological or therapeutic effect. UV absorbent homogeneously distributed as dissolved or dispersed form in the matrix and in the

backing layer. Photosensitive active ingredient is nicotine. TTS has a transparent backing layer and a transparent active substance matrix therefore little noticeable during application to the skin. TTS provides protection of the photosensitive active ingredients against light decomposition. Transparent backing materials are preferably polyester, polyethylene, polypropylene, polyurethane, ethyl Vinyl acetate, or polyethylene terephthalate (PET), as those used by applicant. Matrix materials of the TTS are preferably polyacrylates, polyisobutylenes, polydimethylsiloxanes, or styrene-isoprene-block copolymers, as those used by applicant. Preferred UV absorber is present in amount of 5-10%, and present invention used 7.75% according to table 1. UV absorber includes p-aminobenzoic acid and its derivates, cinnamic acid and its derivatives, and benzophenones. UV absorbers disclosed by the reference read on dyes or pigments since all of them have color (white) as evident by the provides articles: “4-aminobenzoic acid”, encyclopedia; “CINNAMIC ACID”, product identification; and “Benzophenone”, IngredientsFeedbackScience. TTS can be multilayered. TTS applied to the skin and remains there for a long period, for example some hours to several days.

Regarding the claimed lightness color value, such property is inherent to the patch disclosed by Degen being transparent and having the same structure and materials used by applicant. Further, regarding testing of the patch to determine the lightness color value it is not part of the claimed transdermal patch. It is only an in-vitro diagnostic test that is expected to provide the same results obtained from two similar transdermal delivery devices built from the same materials and tested under the same circumstances, and the recitation of this in-vitro test does not impart patentability to

claims directed to transdermal device. The burden is on applicants to show that the claimed testing process resulted in novel and unobvious difference between the claimed product and prior art product since the Patent Office does not have the facilities for preparing the claimed materials and comparing them with the prior art inventions. See *In re Best*, 562 F.2 1252, 195 USPQ 430 (CCPA 1977); and *In re Fitzgerald et al.*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Regarding coating of the dye or pigment on the backing layer as claimed by claim 4 using lacquer as claimed by claim 13, Degen discloses homogenous distribution or solvating the UV absorber in the backing material, and homogenous distribution will provide UV absorber on the surface of the backing forming coating. Lacquer is nothing but solvent, as evident by the definition provided from "Your Dictionary", and solvating the UV absorber in a solvent before application to the backing reads on lacquer claimed by claim 13.

Therefore, all the limitations of the rejected claims are met by Degen's reference.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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